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Takeda drug gets FDA nod for new biologic therapy

22 May 2014 | News | By BioSpectrum Bureau

Singapore: Takeda Pharmaceutical has recieved Food and Drug Administration (FDA) approval for a new biologic therapy, Entyvio (vedolizumab), for the treatment of adults with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD).

"Entyvio is a new option that works to block important contributors to the chronic inflammation that is a hallmark of ulcerative colitis and Crohn's disease," said Mr. Stephen B. Hanauer, medical director, Digestive Health Center, Northwestern University Feinberg School of Medicine. "The clinical trial program evaluated the efficacy and safety profile of Entyvio and demonstrated that Entyvio has the potential to help adult patients with moderately to severely active UC or CD successfully manage their disease."

Entyvio is now approved for inducing and maintaining clinical response and remission, improving endoscopic appearance of the mucosa, and achieving corticosteroid-free remission in adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids. Entyvio is also approved for achieving clinical response and remission and achieving corticosteroid-free remission in adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

"Patients with moderately to severely active ulcerative colitis or Crohn's disease, and the healthcare professionals who care

for them, need additional new treatment options," said Mr. Douglas Cole, president, Takeda Pharmaceuticals U.S.A. "Entyvio reflects an expansion of Takeda's commitment to supporting patients with gastrointestinal disorders."

The Entyvio dose regimen is 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter. Patients should be observed during infusion and until the infusion is complete. See dosage and administration section in full prescribing information.

In March, Entyvio received a positive Opinion for the treatment of adults with moderately to severely active UC and CD from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), and Takeda is awaiting response from the European Commission on approval for Marketing Authorisation.